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EXAMINER

CUTLIFF, YATE KAI RENE

ART UNIT

PAPER NUMBER

1621

NOTIFICATION DATE

DELIVERY MODE

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ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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| | | | |
|------------------------------|--------------------------------------|---|--|
| Office Action Summary | Application No. 10/599,682 | Applicant(s) ISSBERNER ET AL. | |
| | Examiner YATE K. CUTLIFF | Art Unit 1621 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 December 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3, 5, 11, 13 - 21, 23 & 24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3, 5, 11, 13 - 21, 23 & 24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Claims

1. Claims 3, 5, 11, 13 -- 21, 23 and 24 are pending.
Claims 1, 2, 4, 6 – 10, 12 and 22 have been canceled
Claims 3, 5, 11, 13 -- 21, 23 and 24 are rejected.

Response to Amendment

2. The amendment to claims 3, 5, 11, 13, 14, 18, 20 and 21, submitted December 13, 2010 is acknowledged and entered.

Response to Arguments

3. Applicant's arguments, see pages 6 - 8, filed December 13, 2010, with respect to the rejection(s) of claim(s) 3 under 35 USC 103(a) have been fully considered and are persuasive in view of the claim amendment. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Sakurai et al. (US 4,113,635), in view of Memita et al. (US 6,939,980), in view of Andrulis Jr. et al. (US 5,654,312) and further in view of Knothe et al. (American chemical society, 1997) and Linder (US 4,332,702); as set out below.
4. Applicant's arguments, see page 6, filed December 13, 2010, with respect to the 35 USC 103(a) rejections of claims 4 and 22 have been fully considered and are persuasive because the claims have been cancelled. The 35 USC 103(a) rejections of claims 4 and 22 have been withdrawn.

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5. Applicant's arguments with regard to the rejection of claims 5 and 23, filed December 13, 2010 have been fully considered but they are not persuasive. As such claims 5 and 23 remain rejected for the reason set out in the Office Action mailed September 28, 2010 and as set out below.

6. Applicant's arguments, see pages 8 - 10, filed December 13, 2010, with respect to the rejection(s) of claim(s) 11 and 14 - 20 under 35 USC 103(a) have been fully considered and are persuasive in view of the claim amendment. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Sakurai et al. (US 4,113,635), in view of Memita et al. (US 6,939,980), in view of Andrulis Jr. et al. (US 5,654,312) and further in view of Linder (US 4,332,702) and even further in view of Plough, Inc. (EP 0179416) and Bauer et al. (WO 2003/028690A; 2004/0258721); as set out below.

7. Applicant's arguments, see pages 10 - 11, filed December 13, 2010, with respect to the rejection(s) of claim(s) 11 - 13 under 35 USC 103(a) have been fully considered and are persuasive in view of the claim amendment, cancellation claim 12 and arguments. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Sakurai et al. (US 4,113,635), in view of Memita et al. (US 6,939,980), in view of Andrulis Jr. et al. (US 5,654,312) and further in view of Linder (US 4,332,702) and even further in view of Plough, Inc. (EP 0179416) and Bauer et al. (WO 2003/028690A; 2004/0258721); as set out below.

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8. Applicant's arguments, see page 11, filed December 13, 2010, with respect to the rejection(s) of claim(s) 21 and 24 under 35 USC 103(a) have been fully considered and are persuasive in view of the claim amendment. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Sakurai et al. (US 4,113,635), in view of Memita et al. (US 6,939,980), in view of Andrulis Jr. et al. (US 5,654,312), in view of Knothe et al. (American chemical society, 1997), in view of Linder (US 4,332,702) and further in view of in view of Kirk-Othmer (Wiley-Interscience, 1993, vol. 10, 4th ed. page 267); as set out below.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

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were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 5, 3, 21, 23 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sakurai et al. (US 4,113,635), in view of Memita et al. (US 6,939,980), in view of Andrulis Jr. et al. (US 5,654,312), in view of Knothe et al. (American chemical society, 1997) and further in view of Linder (US 4,332,702) and Kirk-Othmer (Wiley-Interscience, 1993, vol. 10, 4th ed. page 267) (Kirk).

13. The rejected claim covers a fatty acid ester mixture of pentaerythritol, wherein the fatty acid component has 6 to 22 carbon atoms, and wherein said ester mixture contains less than 0.3% by weight of esters containing C17 fatty acid acyl groups, and has a melting point of at least 30°C with a percentage content of (a) about 12% to about 19% by weight monoesters, (b) about 25% to about 35% by weight diesters, (c) from about 30% to about 40% by weight triesters, and (d) tetraesters, wherein said fatty acid ester mixture of pentaerythritol is incorporated as a wax component in cosmetic and/or pharmaceutical compositions.

14. Dependent claim 3 limits the weight percentage of C16 and C18 fatty acids in the mixture of fatty acids. Dependent claim 21 states that the fatty acids having 6 to 22 carbon atoms are comprised of unbranched fatty acids. Dependent claims 23 and 24

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further limit the fatty acid ester mixture of pentaerythritol to a mixture of C6-C22 fatty acids.

15. Applicant is reminded that during patent examination, the pending claims must be "given their broadest reasonable interpretation consistent with the specification." In *re Hyatt*, 211 F.3d 1367, 1372, 54 USPQ2d 1664, 1667 (Fed. Cir. 2000). Claim terms are presumed to have the ordinary and customary meanings attributed to them by those of ordinary skill in the art. *Sunrace Roots Enter. Co. v. SRAM Corp.*, 336 F.3d 1298, 1302, 67 USPQ2d 1438, 1441 (Fed. Cir. 2003); *Brookhill-Wilk 1, LLC v. Intuitive Surgical, Inc.*, 334 F.3d 1294, 1298 67 USPQ2d 1132, 1136 (Fed. Cir. 2003). The phrase "contains less than" as applied to C17 fatty acid acyl groups has been interpreted to denote "0 up to 0.3%" C17 fatty acid acyl groups. This means that the ester mixture of claim 5 is free of C17 fatty acid acyl groups. Further, the phrase "has a melting point of at least 30°C" as applied to the fatty acid ester mixture, has been interpreted to denote that this is the start temperature at which the fatty acid ester mixture may begin melting. (see *National Research Development Corporation v. Great Lakes Carbon Corporation, et al.*, 188 USPQ 327 (D. Del. 1975), 410 F. Supp 1108; "At least" one thousand degrees in claim means minimum temperature of one thousand degrees"). Thus, fatty acid ester mixture with a melting temperature above 30°C would fall within the scope of the claim.

16. Further, Applicant has amended claims 3 and 5 to delete the term "from" before the term "about". Applicant is advised that amendment does not narrow the ranges because the term "about" has flexible meaning. In *re DeVaney* held: " In view of the

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flexibility in meaning of the term “about,” however, we are not prepared to accept appellant's insistence that the example given in the Lenher patent of a pH value “maintained at about 7.0” means maintenance at precisely “7.” to be the exact neutrality point” (In re DeVaney, 88 USPQ 97 (CCPA 1950)). Also, In re Ayers held: “The term “about” as used in the patent and in the appealed claim evidently permits of some tolerance.” (In re Ayers, 69 USPQ 109, 154 F2d 182, (CCPA 1946)).

17. Sakurai et al. discloses lubricant compositions of a solid film type, with partial esters of pentaerythritol with fatty acids as the chief constituents, rust-preventative, lubrication-improving agents, surface active agents, etc., having melting points of 30 to 60°C. (see col. 1, lines 11-23). The fatty acids used to produce the corresponding partial esters by the reaction with pentaerythritol are from animal oil, vegetable oils, and straight chain fatty acids i.e. capric (C10), undecanoic (C11), lauric (C12), myristic (C14), palmitic (C16), stearic (C18) and olefinic fatty acids. (see col. 3, lines 40-51). Also, it is stated that most of the partial esters of pentaerythritol of a fatty acid have melting points of less than 60°C. (see col. 3, lines 26-27). Also, it is stated that the partial esters are used in the form of mixtures in industry. (see col. 3, lines 51 - 52). It is stated that the partial ester of pentaerythritol of a fatty acid alone may be used satisfactorily as a lubricant of the solid film for the forming operation. (see col. 3, lines 58 – 60). Example 3 discloses pentaerythritol esters that are 20% monoester, 30% diester, 40% triester and 10% tetraester. According to the results in Table 3 the lubricant of Example 3 exhibited satisfactory results for Sakurai's intended purpose as a

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lubricant. The ranges in Examples 3 overlap Applicant's claimed ranges for the diester, triester and tetraester, and are close to the monoester range.

In the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a prima facie case of obviousness exists. In re Wertheim, 541 F.2d 257, 191 USPQ 90 (CCPA 1976). In this instance the fatty acid component of the prior art encompasses the fatty acid content of Applicant's claimed mixture. Specifically, even though Applicant claims a monoester amount of about 12 - 19%, based on In re DeVaney and In re Ayers, Applicant's monoester range would include 20%.

18. The difference between Applicant's claimed invention and Sakurai et al. is the following: the fatty acid ester mixture of pentaerythritol is incorporated as a wax component in a cosmetic and/or pharmaceutical composition; it does not disclose that the fatty acid is a mixture of fatty acids; it does not disclose the weight percentage of C16 and C18 fatty acids in the mixture and the fatty acids having 6 to 22 carbon atoms are comprised of unbranched fatty acids.

19. However, with regard to the fatty acid ester mixture of pentaerythritol being incorporated as a wax into a cosmetic and/or pharmaceutical composition; the Examiner turns to the teaching of Memita et al. The Memita reference teaches a method for producing ester of pentaerythritol with carboxylic acids having 5 to 30 carbon atoms. (see col. 2, lines 47 - 53 & col. 3, line 22 & 32). Also, it is stated in Memita that esters are used in a wide range of fields such as cosmetics, pharmaceutical preparations, foods, electronic equipment, printing and lubricants. Additionally, Andrulis teaches that a partial fatty acid ester of pentaerythritol monostearate can be used to prepare

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dermally applicable formulations. (see col. 11, lines 16 & 32—34). As such, based on the teachings of Memita and Andrulis it was known in the art at the time of Applicant's claimed invention that fatty acid esters of pentaerythritol whether fully esterified or partially esterified can be incorporated into cosmetic and/or pharmaceutical compositions in addition to the lubricant compositions taught by Sakurai et al.

20. Applicant's claimed fatty acid ester mixture of pentaerythritol and melting ranges are taught by Sakurai et al. Further, Applicant claims an intended use for the fatty acid ester mixture of pentaerythritol by incorporating it as a wax component in cosmetic and/or pharmaceutical composition. However, based on the teachings of Memita and Andrulis, it was known in the art at the time of Applicants claimed invention that fatty acid esters of pentaerythritol can be incorporated into cosmetic and/or pharmaceutical compositions. For this reason one having ordinary skill in the art at the time of Applicant's claimed invention would have a reasonable expectation that the ester mixture of Sakurai et al., which has a similar chemical composition as Applicant's claimed ester mixture, has as an inherent feature that allows it to be incorporated as a wax component of cosmetic and/or pharmaceutical compositions. Further, there is no proof that Applicant's claimed composition possesses unobvious or unexpected properties differing from the properties of the ester mixture taught by Sakurai et al. Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. (In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977)).

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Additionally, "products of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. (In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990)). For this reason, Applicant's claimed invention are obvious in view of the teachings of Sakurai et al., Memita et al. and Andrulis Jr. et al., because incorporation of the fatty acid ester mixture of Sakurai et al. as a wax component in cosmetic and/or pharmaceutical compositions would flow naturally from the ester mixture of Sakurai et al., because Memita teaches that of fatty acid esters of pentaerythritol are known as waxes that have use in cosmetics and pharmaceuticals.

21. With regards to the esters of Sakurai not disclosing that the fatty acid is a mixture of fatty acids, In Example 3 of Sakurai et al, the partial esters were produced from beef tallow. According to the teachings of Knothe et al., which provides an analysis of a variety of natural oils and their fatty acid composition, discloses in Table II on page 179 that the fatty acid composition of beef tallow as a mixture of fatty acids which is generally 3 – 6% C14, 25 to 37% C16 fatty acid and about 14 to 52% C18:0 fatty acid. Based on this fact one of ordinary skill in the art at the time of Applicant's claimed invention would expect that since the esters of Sakurai et al. are made from beef tallow then they would be expected to have a fatty acid composition similar to the beef tallow disclosed by Knothe et al. As such, because of the known fatty acid mixture that is known to be present in beef tallow, Applicant's claimed limitation is deemed to be

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obvious absent a showing of unexpected results. A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). Further, a chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. (*In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990)).

22. With regard to the fatty acid ester mixture of pentaerythritol of Sakurai not disclosing the weight percentage of C16 and C18 fatty acids in the mixture the Examiner turns to the teaching of Lindner. The Lindner reference discloses a partial ester of pentaerythritol, in column 2, lines 45-47 wherein the fatty acid components overlap with Applicant's claimed fatty acid range. Further, Lindner states that these esters are known to be useful as lubricants. (see col. 2, lines 8-9). Additionally, even though Linder states that their partial ester is substantially free of the tetraester, at column 3 lines 38 - 40, it is disclosed that this compound was found to be capable of being present at levels of up to 5 percent by weight (see col. 3, lines 40 – 43. Most importantly, Linder teaches that the ratio of C16 and C18 carbon acids may be adjusted by adding mixtures of pure fatty acids containing C16 and C18 carbon atoms. (see col. 5, lines 60 – 62).

As such, based on the teachings of Lindner, the ratio of C16 fatty acid and C18 fatty acid in Sakurai can be easily adjusted based on the operator's desire. A reference is not limited to its preferred embodiment. (*In re Meinhardt*, 157 USPQ 270, 392 F.2d

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273 (CCPA 1968). Nor is a reference limited to its working examples, but must be evaluated for what it teaches those of ordinary skill in the art. (In re Boe, 148 USPQ 507 355 F2d 961 (CCPA 1966); In re Chapman, 148 USPQ 711, 357 F2d 148 (CCPA 1966). The reference of Sakurai discloses fatty acid esters of pentaerythritol that have an ester content overlapping that of Applicant's. Lindner discloses that the level of C16 and C18 carbon acids can be easily adjusted by the addition of the pure fatty acid. Thus, at the time of Applicant's claimed invention, based on Lindner, it was well within the purview of one having ordinary skill in the art to adjust the level of the C16 and C18 in the fatty acid ester mixture of pentaerythritol of Sakurai.

23. With regard to the fatty acid mixture having fatty acids containing 6 to 22 carbon atoms are comprised of unbranched fatty acids the Examiner turns to the combined teachings of Sakurai and Kirk. In Table 1 of Sakurai et al. one of the esters produced is from coconut oil and hydrogenated beef tallow fatty acid. According to the disclosure of Kirk coconut oil is comprised of unbranched fatty acids of C6 - C18. Also, beef tallow is comprised of unbranched fatty acids of C10 to C20. As such, even though it is not specifically stated that the fatty acids of Sakurai et al. are unbranched, Sakurai et al. produces a mixed ester of pentaerythritol from coconut oil and beef tallow. According to Kirk the fatty acid components of these fats and oils are unbranched. As such, the esters produced from these oils would contain unbranched fatty acid that overlap with Applicant's claimed fatty acid structure. Thus, this limitation is deemed to be obvious absent a showing of unexpected results.

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A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35USC 103(a).

Response to Arguments: (Claims 5 and 23)

24. Applicant respectfully asserts the following:

- a) Examiner failed to teach that Sakurai is a mixture of fatty acids and that the ester of Sakurai is useful in cosmetics and/or pharmaceutical compositions.
- b) Memita discloses fully esterified tetraesters and provides no disclosure of the utility of mixture of partial esters of pentaerythritol in cosmetics and/or pharmaceutical compositions.
- c) Andrulis discloses a pentaerythritol monostearate without disclosing a mixture of partial fatty acid pentaerythritol esters. Nor was there a showing of the benefits of mixtures of partial fatty acid esters of pentaerythritol.

Finally stating that for the above reasons the amended claims are unobvious over the prior art.

25. In response, the Examiner notes that Applicant is arguing against the references individually. One cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. (*In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ

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375 (Fed. Cir. 1986)). Specifically, in view of the fact that Sakurai discloses Applicant's claimed fatty acid ester mixtures of pentaerythritol with the claimed melting ranges.

Also, in view of the fact that according to Memita and Andrulis it was known in the art at the time of Applicant's claimed invention that fatty acid esters of pentaerythritol were useful in compositions of cosmetics and/or pharmaceuticals. As such, for the reasons set out above claims 5, 3, 21 23 and 24 are rejected as being obvious in view of the cited prior art.

26. Claims 11 and 13 - 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sakurai et al. (US 4,113,635), in view of Memita et al. (US 6,939,980), in view of Andrulis Jr. et al. (US 5,654,312) and further in view Linder (US 4,332,702) and even further in view of Plough, Inc. (EP 0179416), and Bauer et al. (WO 2003/028690A; 2004/0258721).

27. The rejected claim covers, inter alia, a cosmetic and/or pharmaceutical composition comprising a wax ester mixture of claim 5. Claim 5 discloses that the wax ester mixture of pentaerythritol has a fatty acid component has 6 to 22 carbon atoms, and wherein said ester mixture contains less than 0.3% by weight of esters containing C17 fatty acid acyl groups, and has a melting point of at least 30°C with a percentage content of (a) about 12% to about 19% by weight monoesters, (b) about 25% to about 35% by weight diesters, (c) from about 30% to about 40% by weight triesters, and (d) tetraesters.

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28. Dependent claim 13 further limits the amount of C6 to C22 fatty acid in the mixture. Dependent claims 14 -19 disclose additional components of the cosmetic or pharmaceutical composition. Dependent claim 20 further limits the cosmetic composition.

29. Applicant is reminded that during patent examination, the pending claims must be "given their broadest reasonable interpretation consistent with the specification." In *re Hyatt*, 211 F.3d 1367, 1372, 54 USPQ2d 1664, 1667 (Fed. Cir. 2000). Claim terms are presumed to have the ordinary and customary meanings attributed to them by those of ordinary skill in the art. *Sunrace Roots Enter. Co. v. SRAM Corp.*, 336 F.3d 1298, 1302, 67 USPQ2d 1438, 1441 (Fed. Cir. 2003); *Brookhill-Wilk 1, LLC v. Intuitive Surgical, Inc.*, 334 F.3d 1294, 1298 67 USPQ2d 1132, 1136 (Fed. Cir. 2003). The phrase "contains less than" as applied to C17 fatty acid acyl groups has been interpreted to denote "0 up to 0.3%" C17 fatty acid acyl groups. This means that the ester mixture of claim 5 is free of C17 fatty acid acyl groups. Further, the phrase "has a melting point of at least 30°C" as applied to the fatty acid ester mixture, has been interpreted to denote that this is the start temperature at which the fatty acid ester mixture may begin melting. (see *National Research Development Corporation v. Great Lakes Carbon Corporation, et al.*, 188 USPQ 327 (D. Del. 1975), 410 F. Supp 1108; "At least" one thousand degrees in claim means minimum temperature of one thousand degrees"). Thus, fatty acid ester mixture with a melting temperature above 30 °C would fall within the scope of the claim.

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30. Further, Applicant has amended claims 5, 13, 14, and 20 to delete the term "from" before the term "about". Applicant is advised that amendment does not narrow the ranges because the term "about" has flexible meaning. In *re DeVaney* held: "In view of the flexibility in meaning of the term 'about,' however, we are not prepared to accept appellant's insistence that the example given in the Lenher patent of a pH value 'maintained at about 7.0' means maintenance at precisely '7.' to be the exact neutrality point" (In *re DeVaney*, 88 USPQ 97 (CCPA 1950)). Also, In *re Ayers* held: "The term 'about' as used in the patent and in the appealed claim evidently permits of some tolerance." (In *re Ayers*, 69 USPQ 109, 154 F2d 182, (CCPA 1946)).

31. Sakurai et al. discloses lubricant compositions of a solid film type, with partial esters of pentaerythritol with fatty acids as the chief constituents, rust-preventative, lubrication-improving agents, surface active agents, etc., having melting points of 30 to 60°C. (see col. 1, lines 11-23). The fatty acids used to produce the corresponding partial esters by the reaction with pentaerythritol are from animal oil, vegetable oils, and straight chain fatty acids i.e. capric (C10), undecanoic (C11), lauric (C12), myristic (C14), palmitic (C16), stearic (C18) and olefinic fatty acids. (see col. 3, lines 40-51). Also, it is stated that most of the partial esters of pentaerythritol of a fatty acid have melting points of less than 60°C. (see col. 3, lines 26-27). Also, it is stated that the partial esters are used in the form of mixtures in industry. (see col. 3, lines 51 - 52). It is stated that the partial ester of pentaerythritol of a fatty acid alone may be used satisfactorily as a lubricant of the solid film for the forming operation. (see col. 3, lines 58 - 60). Example 3 discloses pentaerythritol esters that are 20% monoester, 30%

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diester, 40% triester and 10% tetraester. According to the results in Table 3 the lubricant of Example 3 exhibited satisfactory results for Sakurai's intended purpose as a lubricant. The ranges in Examples 3 overlap Applicant's claimed ranges for the diester, triester and tetraester, and are close to the monoester range.

In the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a prima facie case of obviousness exists. In re Wertheim, 541 F.2d 257, 191 USPQ 90 (CCPA 1976). In this instance the fatty acid component of the prior art encompasses the fatty acid content of Applicant's claimed mixture. Specifically, even though Applicant claims a monoester amount of about 12 - 19%, based on In re DeVaney and In re Ayers, Applicant's monoester range would include 20%.

32. The difference between Applicant's claimed invention and Sakurai is as follows: the wax ester mixture of claim 5 being a cosmetic and/or pharmaceutical composition; the C6-22 fatty acid (FA) having about 40% to 50% by weight C16 FA and about 45% to 55% C18 FA; the percentage of wax ester in the composition; the use of an additional wax component i.e. partial glycerides; the use of a nonionic surfactant i.e. alkyl or alkenyl oligoglycosides; an oil component that is liquid at 25°C; and the composition having the features of claim 20.

33. However, with regard to the wax ester mixture of claim 5 being a cosmetic and/or pharmaceutical composition the Examiner turns to the teachings of Memita and Andrulis. The Memita reference teaches a method for producing ester of pentaerythritol with carboxylic acids having 5 to 30 carbon atoms. (see col. 2, lines 47 - 53 & col. 3, line 22 & 32). Also, it is stated in Memita that esters are used in a wide range of fields

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such as cosmetics, pharmaceutical preparations, foods, electronic equipment, printing and lubricants. Additionally, Andrulis teaches that a partial fatty acid ester of pentaerythritol monostearate can be used to prepare dermally applicable formulations. (see col. 11, lines 16 & 32—34). As such, based on the teachings of Memita and Andrulis it was known in the art at the time of Applicant's claimed invention that fatty acid esters of pentaerythritol whether fully esterified or partially esterified can be incorporated into cosmetic and/or pharmaceutical compositions in addition to the lubricant compositions taught by Sakurai et al.

34. Applicant's claimed fatty acid ester mixture of pentaerythritol and melting ranges are taught by Sakurai et al. Further, based on the teachings of Memita and Andrulis, it was known in the art at the time of Applicants claimed invention that fatty acid esters of pentaerythritol can be incorporated into cosmetic and/or pharmaceutical compositions. For this reason one having ordinary skill in the art at the time of Applicant's claimed invention would have a reasonable expectation that the ester mixture of Sakurai et al., which has a similar chemical composition as Applicant's claimed ester mixture, has as an inherent feature that allows it to be incorporated as a wax component of cosmetic and/or pharmaceutical compositions. Further, there is no proof that Applicant's claimed composition possesses unobvious or unexpected properties differing from the properties of the ester mixture taught by Sakurai et al.

Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been

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established. (In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977)).

Additionally, "products of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable.

Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. (In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990)).

Furthermore, the discovery of a new use for an old structure based on unknown properties of the structure might be patentable to the discoverer as a process of using. In re Hack, 245 F.2d 246, 248, 114 USPQ 161, 163 (CCPA 1957). However, when the claim recites using an old composition or structure and the "use" is directed to a result or property of that composition or structure, then the claim is anticipated. In re May, 574 F.2d 1082, 1090, 197 USPQ 601, 607 (CCPA 1978) (Claims 1 and 6, directed to a method of effecting nonaddictive analgesia (pain reduction) in animals, were found to be anticipated by the applied prior art which disclosed the same compounds for effecting analgesia but which was silent as to addiction. The court upheld the rejection and stated that the applicants had merely found a new property of the compound and such a discovery did not constitute a new use. The court went on to reverse the rejection of claims 2-5 and 7-10 which recited a process of using a new compound. The court relied on evidence showing that the nonaddictive property of the new compound was unexpected.). Therefore, for the reasons set out in paragraphs 29, 30 33 and 34, Applicant's claimed invention are obvious in view of the teachings of Sakurai et al., Memita et al. and Andrulis Jr. et al.

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35. With regard the C6-22 fatty acid (FA) having about 40% to 50% by weight C16 FA and about 45% to 55% C18 FA, the Examiner turns to the teaching of Lindner. The Lindner reference Lindner discloses a partial ester of pentaerythritol, in column 2, lines 45-47 wherein the fatty acid components overlap with Applicant's claimed fatty acid range. Further, Lindner states that these esters are known to be useful as lubricants. (see col. 2, lines 8-9). Additionally, even though Linder states that their partial ester is substantially free of the tetraester, at column 3 lines 38 – 40, it is disclosed that this compound was found to be capable of being present at levels of up to 5 percent by weight (see col. 3 lines 40 – 43). Most importantly, Linder teaches that the ratio of C16 and C18 carbon acids may be adjusted by adding mixtures of pure fatty acids containing C16 and C18 carbon atoms. (see col. 5, lines 60 – 62).

As such, based on the teachings of Lindner, the ratio of C16 fatty acid and C18 fatty acid in Sakurai can be easily adjusted based on the operator's desire. A reference is not limited to its preferred embodiment. (In re Meinhardt, 157 USPQ 270, 392 F.2d 273 (CCPA 1968). Nor is a reference limited to its working examples, but must be evaluated for what it teaches those of ordinary skill in the art. (In re Boe, 148 USPQ 507 355 F2d 961 (CCPA 1966); In re Chapman, 148 USPQ 711, 357 F2d 148 (CCPA 1966). The reference of Sakurai discloses fatty acid esters of pentaerythritol that have an ester content overlapping that of Applicant's. Lindner discloses that the level of C16 and C18 carbon acids can be easily adjusted by the addition of the pure fatty acid from. Thus, at the time of Applicant's claimed invention, based on Lindner, it was well within the purview of one having ordinary skill in the art to adjust the level of the C16

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and C18 in the fatty acid ester mixture of pentaerythritol of Sakurai; and wherein Memita teaches that these esters can be incorporated into cosmetics.

36. With regard to the percentage of wax ester in the composition; the use of an additional wax component i.e. partial glycerides, the use of a nonionic surfactant i.e. alkyl or alkenyl oligoglycosides, an oil component that is liquid at 25 °C, and the composition having the features of claim 20; the Examiner turns to the teachings of Plough and Bauer. Plough discloses cosmetic and cosmetic based compositions which contain pentaerythritol esters, where the fatty acid acyl group is C20 to C24, and include a wax component, a non ionic surfactant, and an oil component. The Plough reference discloses a long ware cosmetic that uses pentaerythritol tetra (C20-C24) aliphatic hydrocarbon carboxylate. (see page 1, paragraph 3). Also, the composition of Plough includes waxes (page 3, para. 3), cetyl alcohol (page 3, last line), sucroglycerides (see page 4, para. continued from page 3), oils (page 4, para. 1), and nonionic surfactants (page 5, para. 6). Applicant is directed to Examples I—VI.

Also, with regard to the use of pentaerythritol esters in cosmetic compositions and where the wax component of the composition is a C12-C24 partial glyceride, the Examiner turned to the teaching of Bauer et al. The Bauer et al. reference discloses a cosmetic or dermatological stick that includes pentaerythritol tetraisosterate and polyglyceryl-3 diisostearate along with other known additives useful in the cosmetic industry; and use of the other components in weight percentage ranges that overlap with Applicant's claimed ranges. Applicant is directed to the disclosure of Examples 93 and 96 on page 46 of Bauer.

Therefore, based on the teachings of Plough and Bauer et al., it would have been obvious to one having ordinary skill in the art at the time of Applicant's claimed invention to prepare cosmetic and/or pharmaceutical compositions that was comprised of a pentaerythritol fatty acid ester of the type disclosed by the teachings of Sakurai; prepare cosmetic compositions with those esters and include other components known to be useful in the cosmetic and/or pharmaceutical industry as suggested by Plough and Bauer et al. in the cosmetic composition.

Response to Arguments: (Plough and the Declaration of October 19, 2009)

37. Applicant respectfully asserts that the declaration disclosed comparative testing with Plough to show that Applicant's ester provided a stable cosmetic emulsion.

38. In response, the Examiners comments set out in the Final Rejection mailed February 4, 2010 are reproduced below.

The Declaration of Helga Gondek under 37 CFR 1.132 filed October 19, 2009 is insufficient to overcome the rejection of claims 11 - 20 based upon Plough reference as set forth in the last Office Action and as set out below, because: Applicant only compared their claimed pentaerythritol ester mixture of C18 and C16 to a pentaerythritol ester of C22 of Plough. Applicant's claimed invention of claims 11 - 20 is not limited to partial esters of pentaerythritol, i.e. mono, di, or triesters, but, can include tetraesters. Plough teaches the use of fatty acids of C20 to C24. Further, Applicant's claim ester is not limited to ester mixture with C16 and C18 fatty acids but, includes the range of esters of fatty acids from C6 to C22, which overlaps with the fatty acids of Plough. As, such the comparison provided in the Declaration does not demonstrate that there would

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be instability of an emulsion within the overlapping fatty acid ranges of their claimed invention and the pentaerythritol esters of Plough. Furthermore, the comparison with Plough is not a comparison with the closest prior art. In view of the foregoing, when all of the evidence is considered, the totality of the rebuttal evidence of nonobviousness fails to outweigh the evidence of obviousness.

39. For the reasons set out above in paragraphs 29, 30, 31 and 33 - 36 claims 11, and 13 - 20 are rejected.

Conclusion

40. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to YATE K. CUTLIFF whose telephone number is (571)272-9067. The examiner can normally be reached on M-TH 8:30 a.m. - 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Daniel M. Sullivan can be reached on (571) 272 - 0779. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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